

### **REMARKS**

Claims 21-32 and 57-81 are pending in the application. Claims 21-32 and 57-81 have been rejected. Reconsideration and withdrawal of the rejections set forth in the Office action dated May 7, 2003 are respectfully requested.

Submitted with this response is a Petition for a 2-Month extension of time.

#### **I. Amendments**

Claims 21, 60, 71 are amended to include the feature that the targeting ligand has "binding affinity for a receptor expressed on a cell", as set forth on page 9, lines 4-5.

#### **II. Rejection under 35 U.S.C. §102**

Claims 21-25, 60, and 71 were rejected under 35 U.S.C. §102(a) as allegedly anticipated by Torchilin *et al.* (U.S. Patent No. 5,534,241). This rejection is respectfully traversed for the following reasons.

Summaries of the instant claims and of the Torchilin *et al.* document are provided in Applicants' response submitted January 3, 2002.

##### **A. Analysis of the Rejection**

According to the M.P.E.P. § 2131, "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference."

Torchilin *et al.* describe a polychelating compound for use in liposomes or micelles. The polychelating compound is comprised of a lipid, a polymer, and a metal chelating agent linked to the polymer (Col. 1, lines 40-48).

The present invention as embodied in the newly amended claims is directed to a conjugate comprised of a lipid, a polymer, and a targeting ligand having binding affinity for a receptor expressed on a cell.

Since the polychelating agent of Torchilin *et al.* does not have "binding affinity for a receptor expressed on a cell", the reference fails to disclose each and every element

of the claims. Thus, the standard for anticipation has not been met and withdrawal of the rejection under 35 U.S.C. §102(a) is respectfully requested.

### III. Rejection under 35 U.S.C. §103

Claims 21-32 and 57-81 were rejected under 35 U.S.C. §103 as allegedly obvious over Torchilin *et al.* further in view of Harris *et al.* (U.S. Patent No. 5,932,462). This rejection is respectfully traversed for the following reasons.

Summaries of the present invention and the cited art are provided in Applicants' response submitted January 3, 2002.

#### A. Analysis

The Examiner asserts that it would have been obvious to use any targeting molecule in the polymer complex of Torchilin *et al.* with the expectation of obtaining at least similar results since Harris *et al.* teach that any ligand can be coupled to the hydrophilic polymer system.

As noted above, the present claims are modified to require that the targeting ligand has binding affinity for a receptor expressed on a cell.

Torchilin *et al.* describes a lipid-polymer-polychelating agent, where the polychelating agent has no binding affinity for a receptor expressed on a cell. The chelating agent in Torchilin *et al.* is a metal-chelating agent used as a radiocontrast agent. Nothing in Torchilin *et al.* teaches that the agent has "binding affinity" for a receptor expressed on a cell.

Nor does it make sense to modify Torchilin *et al.* according to the teaching of Harris *et al.* Harris *et al.* describes a multi-armed monofunctional polymer having a single reactive site (moiety "Z" in the structure of the abstract and claim 1) and two nonreactive polymer arms. The single reactive site means that the polymer cannot be a link between a lipid and a polymer, as needed to combine with Torchilin *et al.* to arrive at the present invention.

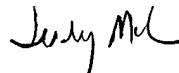
Thus, the combination of Torchilin *et al.* and Harris *et al.* fail to teach a lipid-polymer-targeting agent. Accordingly, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. §103.

**CONCLUSION**

It is respectfully submitted that each of the pending claims 21-32 and 57-81 are in condition for allowance. A Notice of Allowance is respectfully requested.

The Examiner is invited to contact Applicants' representative at (650) 838-4402 as needed.

Respectfully submitted,



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Date: October 3, 2003

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